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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/660,206	09/10/2003	Carl T. Wild	11613.64USC1	7645

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EXAMINER	
PARKIN, JEFFREY S	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 06/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/660,206	WILD ET AL.	
	Examiner	Art Unit	
	Jeffrey S. Parkin, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 03 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 April 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-62* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☒ Claim(s) *42 and 43* is/are objected to.

8)☒ Claim(s) *25-41 and 44-62* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Restriction Requirement

37 C.F.R. § 1.75(c)

Claims 42 and 43 are objected to under 37 C.F.R. § 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only, and/or, cannot depend from any other multiple dependent claim, and/or, does not refer to a preceding claim, and/or, references two sets of claims with different features. See M.P.E.P. § 608.01(n). Accordingly, the claims have not been further treated on the merits. Applicant(s) is/are required to cancel the claim(s), or amend the claim(s) to place the claims in proper dependent form, or rewrite the claim(s) in independent form.

35 U.S.C. § 121

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

a. Group I, claim(s) 25-28, drawn to a polypeptide **conjugate** comprising both N-helical and C-helical domain HIV gp41 polypeptides, classified in class 424, subclass 196.11.

b. Group II, claim(s) 29, drawn to an anti-conjugate **antibody**, classified in class 530, subclasses 388.35 and 389.4.

c. Group III, claim(s) 20-32, drawn to a polypeptide **mixture** comprising both N-helical and C-helical domain HIV gp41 polypeptides, classified in class 424, subclass 202.1.

d. Group IV, claim(s) 33, drawn to an anti-polypeptide mixture **antibody**, classified in class 530, subclasses 388.35 and 389.4.

e. Group V, claim(s) 34, drawn to a **method** of **treating** an HIV-infected individual by administering **anti-conjugate antibodies**, classified in class 424, subclass 130.1.

f. Group VI, claim(s) 34, drawn to a **method** of **treating** an HIV-infected individual by administering **anti-polypeptide antibodies**, classified in class 424, subclass 130.1.

g. Group VII, claim(s) 35-40, drawn to isolated **nucleic acids** encoding a polypeptide conjugate, classified in class 536, subclass 23.72.

h. Group VIII, claim(s) 41, drawn to a **method** of **making** a **polypeptide** conjugate, classified in class 435, subclass 69.1.

i. Group IX, claim(s) 44-48, drawn to a **method** of **making antibodies** specific for HIV gp41 **N-helical** polypeptides, classified in class 435, subclasses 326 and 339.1.

j. Group X, claim(s) 49-54, drawn to a **method** of **making antibodies** specific for HIV gp41 **C-helical** polypeptides, classified in class 435, subclasses 326 and 339.1.

k. Group XI, claim(s) 55 and 56, drawn to a method of making gp41-specific antibodies by administering a polypeptide **mixture** comprising both N-helical and C-helical domain HIV gp41 polypeptides, classified in class 435, subclasses 326 and 339.1.

l. Group XII, claim(s) 57-62, drawn to a method of making gp41-specific antibodies by administering a polypeptide **conjugate** comprising both N-helical and C-helical domain HIV gp41 polypeptides, classified in class 435, subclasses 326 and 339.1.

The inventions are distinct, each from the other because of the following reasons:

Unrelated Inventions

Inventions I-IV and VII are all are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04 and § 808.01). In the instant case, each of the identified groups is directed toward a structurally and functionally different product

(e.g., polypeptide conjugates, polypeptide mixtures, antibodies, nucleic acids). Separate searches will clearly be required for each group. Therefore, each group is clearly directed toward a different inventive concept.

Inventions V, VI, and VIII-XII are all unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04 and § 808.01). In the instant case, each of the identified methods is directed toward a different scientific objective (e.g., treatment or production of antibodies) and will employ different reagents (e.g., antibodies, polypeptides, polypeptide conjugates) and protocols. Separate searches will also be required for each group. Accordingly each group is clearly directed toward a different inventive entity.

Inventions I/III/IV/VII and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04 and § 808.01). In the instant case, the method of group V neither requires nor utilizes the products of groups I, III, IV, and VII.

Inventions I/II/III/VII and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04 and § 808.01). In the instant case, the method of group VI neither requires nor utilizes the products of groups I, II, III, and VII.

Inventions II-IV/VII and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04 and § 808.01). In the instant case, the method of group VIII neither requires nor utilizes the products of groups II, III, IV, and VII.

Inventions I/II/IV/VII and XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04 and § 808.01). In the instant case, the method of group XI neither requires nor utilizes the products of groups I, II, IV, and VII.

Inventions II-IV/VII and XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04 and § 808.01). In the instant case, the method of group XII neither requires nor utilizes the products of groups II, III, IV, and VII.

Product and Process of Making

Inventions I and VIII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (M.P.E.P. § 806.05(f)). In the instant case, the polypeptide conjugate can be prepared through solid-phase peptide synthesis or through chemical modification of synthetic peptides.

Product and Process of Using

Inventions II and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the antibodies of group I can be employed in a materially different process such as immunological assays for the detection of viral antigens.

Inventions IV and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the antibodies of group IV can be employed in a materially different process such as immunological assays for the detection of viral antigens.

Inventions III and XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the peptide immunogens can be employed in a materially different process such as antibody capture assays to detect viral-specific antibodies.

Inventions I and XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the peptide conjugates can be employed in a materially different process such as antibody capture assays to detect viral-specific antibodies.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, recognized divergent subject matter, and require separate searches, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. § 1.143). Applicant is also advised that the claims should be amended to reflect the election, where necessary.

37 C.F.R. § 1.48(b)

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(i).

Claim Rejoinder (M.P.E.P. § 821.04)

Applicants are reminded that a restriction between product and process claims has been set forth *supra*. When applicant elects claims directed to the product, and a product claim is subsequently found to be allowable, withdrawn process claims that depend from or otherwise include **all** the limitations of the allowable product claim will be rejoined in accordance with the provisions of § 821.04 of the M.P.E.P. Process claims that depend from or otherwise include **all** the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 C.F.R. § 1.116 while amendments submitted after allowance are governed by 37 C.F.R. § 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 C.F.R. § 1.104. Thus, to be allowable, the rejoined claims **must** meet all criteria for patentability as set forth under 35 U.S.C. §s 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. **Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined.** See AGuidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer*, and 35 U.S.C. § 103(b), 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product

claims. **Failure to do so will result in a loss of the right to rejoinder.** Furthermore, note that the prohibition against double patenting rejections of 35 U.S.C. § 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See M.P.E.P. § 804.01.

Correspondence

Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (571) 272-0908. The examiner can normally be reached Monday through Thursday from 10:30 AM to 9:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Bruce R. Campell, Ph.D., can be reached at (571) 272-0974. Direct general status inquiries to the Technology Center 1600 receptionist at (571) 272-1600. Informal communications may be submitted to the Examiner's RightFAX account at (571) 273-0908.

Applicants are reminded that the United States Patent and Trademark Office (Office) requires most patent related correspondence to be: a) faxed to the Central FAX number (571-273-8300) (updated as of July 15, 2005), b) hand carried or delivered to the Customer Service Window (now located at the Randolph Building, 401 Dulany Street, Alexandria, VA 22314), c) mailed to the mailing address set forth in 37 C.F.R. § 1.1 (e.g., P.O. Box 1450, Alexandria, VA 22313-1450), or d) transmitted to the Office using the Office's Electronic Filing System. This notice replaces all prior Office notices specifying a specific fax number or hand carry address for certain patent related correspondence. For further information refer to the Updated Notice of Centralized Delivery and Facsimile Transmission Policy for Patent Related Correspondence, and Exceptions Thereto, 1292 Off. Gaz. Pat. Office 186 (March 29, 2005).

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see

http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,

Jeffrey S. Parkin, Ph.D.
Primary Examiner
Art Unit 1648

24 June, 2006